

June 27, 2003

Edwin L. Mongan, III  
Manager, Environmental Stewardship  
E.I. du Pont Nemours & Company, Inc.  
1007 Market Street, DuPont 6082  
Wilmington, DE 19898

Dear Mr. Mongan:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Reaction Product (Cyclododecanol/Cyclododecanone/Nitric Acid), High-Boiling Fraction (Corfree) posted on the ChemRTK HPV Challenge Program Web site on January 29, 2003. I commend E.I. du Pont Nemours & Company, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that E.I. du Pont Nemours & Company, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us@" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: W. Penberthy  
M. E. Weber

## **EPA Comments on Chemical RTK HPV Challenge Submission: Corfree® M1**

### **Summary of EPA Comments**

The sponsor, E.I. du Pont de Nemours & Company, Inc., submitted a test plan and robust summaries to EPA for Reaction Product (cyclododecanol/cyclododecanone/nitric acid), high-boiling fraction (Corfree® M1, CAS No. 7262-23-3) dated December 19, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 29, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. Adequate data are available for all endpoints for the purposes of the HPV Challenge Program. EPA recommends that the submitter provide data on the dissociation constant ( $pK_a$ ) for dodecanedioic acid.
2. Environmental Fate. Adequate data are available for all endpoints for the purposes of the HPV Challenge Program except for photodegradation. The submitter needs to provide estimated photodegradation data for dodecanedioic acid.
3. Health Effects. Adequate data are available for all endpoints for the purposes of the HPV Challenge program. The submitter needs to address a few deficiencies in the robust summaries.
4. Ecological Effects. Although the submitted data have several deficiencies, the submitted data and SAR analyses address the endpoints for the purposes of the HPV Challenge Program. The submitter needs to provide the input values it used in ECOSAR.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### **EPA Comments on the Corfree® M1 Challenge Submission**

#### **Substance Description**

The sponsored substance is a reaction product (cyclododecanol/cyclododecanone/nitric acid), high-boiling fraction (CAS No. 7262-23-3), referred to as Corfree® M1. Corfree® M1 is a mixture of dibasic acids, and is composed primarily of dodecanedioic acid (DDDA, CAS No. 693-23-2, approx. 38-49%), undecanedioic acid (CAS No. 1852-04-6, approx. 31-38%) and decanedioic acid (sebacic acid, CAS No. 111-20-6, approx. 5-7%). DDDA is the largest component of Corfree® M1 and it is expected to have similar physicochemical, environmental, and toxicological properties to those for the other major components. Therefore, the submitter states that DDDA data can be used to address several endpoints. Dodecanedioic, undecanedioic, and decanedioic acids are straight chain  $C_{12}$ ,  $C_{11}$ , and  $C_{10}$  diacids, respectively.

#### **Test Plan**

#### Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data for melting point, boiling point, vapor pressure, octanol/water partition coefficient and water solubility are adequate for the purposes of the HPV Challenge Program. EPA recommends that the submitter provide data for the dissociation constant ( $pK_a$ ) of dodecanedioic acid according to OECD TG 112. The dissociation constant is important in adsorption of chemicals to soils and sediments as well as in cellular absorption.

#### Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for stability in water, biodegradation, and transport and distribution (fugacity) are adequate for the purposes of the HPV Challenge Program.

*Photodegradation.* In Table 1 of the test plan, the submitter indicates that adequate photodegradation data are available for Corfree M1 and dodecanedioic acid. However, the robust summaries provide only qualitative statements on this endpoint. The submitter needs to provide estimated atmospheric oxidation and photolysis data for dodecanedioic acid.

#### Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

All health effects endpoints have been adequately addressed by data submitted for Corfree® M1 or DDDA for the purposes of the HPV Challenge Program; however, the submitter needs to address a few deficiencies in the robust summaries.

#### Ecological Effects (fish, invertebrates, and algae)

The use of dodecanedioic acid data to characterize the ecotoxicity of Corfree® M1 is appropriate. Although the submitted data have several deficiencies, the measured and estimated values show that this chemical has low toxicity. The submitted information addresses the fish, aquatic invertebrates, and algae acute toxicity endpoints for the purposes of the HPV Challenge Program.

*Fish and Invertebrates.* The fish and daphnia acute toxicity tests were conducted with shorter (48-hour fish, 24-hour daphnia) than required (96-hour fish, 48-hour daphnia) test durations. Although no new testing is proposed, EPA agrees with the submitter that this chemical is expected to show low toxicity based on measured data and the ECOSAR predicted values ( $>100$  mg/L). The submitter, however, needs to provide model input parameters for the ECOSAR predictions.

*Algae.* The adequacy of the submitted algal toxicity data could not be determined because the test was done below the chemical's water solubility limit. Although no new testing is proposed, EPA agrees with the submitter that this chemical is expected to show low toxicity which is supported by the ECOSAR predicted value ( $>100$  mg/L). The submitter, however, needs to provide model input parameters for the ECOSAR predictions.

#### **Specific Comments on the Robust Summaries**

##### Physicochemical Properties

*Biodegradation.* In the robust summaries, the submitter needs to provide substance concentration, inoculum concentration and test temperature.

### Health Effects

*Genetic Toxicity.* A robust summary for a gene mutation assay on DDDA had the following omissions: test substance purity, concentrations tested, cytotoxic concentrations, number of replicates, and criteria for assessing results.

### Ecological Effects

The submitter needs to provide the model input parameters for ECOSAR predictions of fish, invertebrates, and algal toxicity values.

### **Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.